

**Notice of Allowability**

Application No.

10/763,619

Examiner

WILLIAM W. MOORE

Applicant(s)

RUMENAPF ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 17 January 2008 and the interview conducted 15 February 2008.

2. ☒ The allowed claim(s) is/are 1-12 and 14-18.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_

4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_

## EXAMINERS AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Amend claims 1, 5, and 6 thus:

1. (Amended) A nucleic acid molecule coding for a fusion protein comprising a first polypeptide which is a pestivirus autoprotease N<sup>Pro</sup> and a second polypeptide which is covalently bound to the first polypeptide at the C-terminus of the first polypeptide in a manner such that the second polypeptide is capable of being cleaved from the fusion protein by the autoproteolytic activity of the first polypeptide, and where the second polypeptide is a heterologous with respect to the first polypeptide wherein said C-terminus of said first polypeptide is a cysteine at a position corresponding to position 168 of SEQ ID NO:1.

Claim 5 (Amended): A nucleic acid molecule according to claim 1, wherein the first polypeptide consists of an amino acid sequence corresponding to the amino acid sequence Glu22 to Cys168 of the autoprotease N<sup>Pro</sup> of classical swine fever virus and wherein the first polypeptide additionally has a Met as N-terminus, wherein said positions are determined by correspondence to positions 22 and 168 of SEQ ID NO:1

Claim 6 (Amended): A nucleic acid molecule according to claim 1, wherein the first polypeptide comprises an amino acid sequence corresponding to the amino acid sequence Pro17 to Cys168 of the autoprotease N<sup>Pro</sup> of classical swine fever virus herein the first polypeptide has a Met as N-terminus wherein said positions are determined by correspondence to positions 17 and 168 of SEQ ID NO:1.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Mark I. Bowditch on 15 February 2008.

The following is an examiner's statement of reasons for allowance:

Claims 1, 5, and 6 are amended above to clarify the intended subject matter by indicating the disclosed amino acid sequence with which positional correspondence can be determined. This ensures that the single disclosed embodiment of an auto-processing amino-terminal protease within the broad genus of pestiviral auto-processing amino-terminal proteases that may be used according to the teaching of the specification extends to the members of that genus having the necessary structural components that support the intended function. The members of this genus extend beyond the strains of pestivirus isolated from sources recited in

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claim 2 according to Hughes, 2004, made of record herewith, who establishes that pestiviruses having auto-processing amino-terminal proteases infect other ungulates, such as reindeer and giraffes, see Figure 1 at page 330. Thiel et al., 1992, and Scaramozzino et al., 2002, are similarly made of record herewith for their teachings that taxonomic classification of the positive-polarity, single-stranded, RNA viruses particularly defines pestiviruses by the presence at the amino-terminus of an expressed viral polyprotein of a "non-structural" auto-processing protease. See Figure 4 of Thiel et al. showing that structural proteins, i.e., not proteases, are defining features of other genera of positive-polarity, single-stranded, RNA viruses otherwise structurally similar to the pestivirus genus as well as Figure 2 of Scaramozzino et al. where the designation "C" indicates that "capsid" proteins are present at the amino-termini of polyproteins encoded by the flavivirus and hepacivirus genera while the amino terminus of polyproteins encoded by the genus pestivirus require an auto-processing cysteine protease at their amino termini. Thus claims 1-12 and 14-18 are allowed herewith.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### *Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

/Nashed/  
Nashaat T. Nashed, Ph.D.  
Supervisory Patent Examiner  
Art Unit 1652

William W. Moore  
15 February 2008